Claims

1. An oral pharmaceutical dosage form comprising a H^+, K^+-ATPase inhibitor and a gastric antisecretory prostaglandin analogue compound and optionally pharmaceutically acceptable excipients, wherein the dosage form is in the form of a fixed unit dosage form comprising at least these two pharmaceutically active components.

2. A dosage form according to claim 1, wherein the dosage form is a tablet formulation.

3. A dosage form according to claim 1, wherein the dosage form is a capsule formulation.

4. A dosage form according to any of claims 1-3, wherein the H^+, K^+-ATPase inhibitor compound is protected by an enteric coating layer, and optionally a separating layer is applied under the enteric coating separating the H^+, K^+-ATPase inhibitor from the enteric coating layer.

5. A dosage form according to claim 1, wherein the fixed dosage form in addition to the H^+, K^+-ATPase inhibitor and the gastric antisecretory prostaglandin analogue comprises a calcium channel blocking agent.

6. A dosage form according to any of claims 1-5, wherein the H^+, K^+-ATPase inhibitor is omeprazole, an alkaline salt thereof, one of its single enantiomer or an alkaline salt thereof.

7. A dosage form according to claim 6, wherein the H^+, K^+-ATPase inhibitor is omeprazole magnesium salt.

8. A dosage form according to claim 6, wherein the H^+, K^+-ATPase inhibitor is S-omeprazole magnesium salt.

9. A dosage form according to any of claims 1-5, wherein the H^+, K^+-ATPase inhibitor is lansoprazole, or one of its single enantiomers or a pharmaceutically acceptable salt thereof.

10. A dosage form according to any of claims 1-5, wherein the H^+, K^+-ATPase inhibitor is pantoprazole, or one of its single enantiomers or a pharmaceutically acceptable salt thereof.

11. A dosage form according to one of claims 1-10, wherein the gastric antisecretory prostaglandin analogue compound is misoprostol, enisoprost, enprostil or one of the single enantiomers thereof or a pharmaceutical acceptable salt thereof.

12. A dosage form according to any of claims 1-11, wherein the amount of the H^+, K^+-ATPase inhibitor is in the range of 1-200 mg and the amount of the gastric antisecretory prostaglandin analogue is in the range of 80 - 1 000 µg.

13. A dosage form according to any of claims 1-12, wherein the amount of the H^+, K^+-ATPase inhibitor is in the range of 5-80 mg and the amount of the gastric antisecretory prostaglandin analogue is in the range of 100-800 µg.

14. A tableted dosage form according to claim 2, wherein the tablet consists of two different layers, a first layer comprising the H^+, K^+-ATPase inhibitor and a second layer comprising the gastric antisecretory prostaglandin analogue.

15. A tableted dosage form according to claim 2, wherein the tablet formulation is a multiple unit tableted dosage form comprising

a) the H^+, K^+-ATPase inhibitor in the form of enteric coating layered pellets,

b) the gastric antisecretory prostaglandin analogue compound and optionally

c) pharmaceutically acceptable excipients

compressed together into a tablet, whereby the enteric coating layer covering the individual pellets has mechanical properties such that the tableting of the pellets together with the gastric antisecretory prostaglandin analogue and optionally pharmaceutically acceptable excipients does not significantly affect the acid resistance of the enteric coating layered pellets.

16. A tableted dosage form ~~according~~ according to claim 15, wherein the enteric coating of the individual pellets comprises a plasticized enteric coating layer material.

17. A tableted dosage form according to claim 15, wherein the enteric coating layered pellets are further covered with an over-coating layer comprising a film forming polymer and pharmaceutically acceptable excipients.

18. A tableted dosage form according to any of claims 15-17, wherein the tablet is divisible.

19. A tableted dosage form according to claim 2, wherein at least one part of the tablet is in the form of an extended release formulation.

20. A tablet dosage form according to claim 19, wherein the part of the tablet giving extended release is a hydrophilic matrix.

21. A tablet dosage form according to claim 19, wherein the part of the tablet giving extended release is a hydrophobic matrix.

22. A tablet dosage form according to claim 2, wherein the tablet consists of two different layers, a first layer comprising the H^+, K^+-ATPase inhibitor in the form of enteric

coating layered pellets compressed with tablet excipients into a layer, and a second layer giving an extended release of the incorporated gastric antisecretory prostaglandin analogue.

23. A tableted dosage form according to claim 2, wherein the tablet comprises enteric coating layered pellets of the H^+, K^+-ATPase inhibitor layered with a further layer comprising the gastric antisecretory prostaglandin analogue, and the layered pellets are compressed with tablet excipients to a tablet.

24. A tableted dosage form according to claim 23, wherein the pellets before compression to a tablet is covered by a pigmented film coating layer, or the compressed tablet is covered by a pigmented tablet coat.

25. A tablet dosage form according to claim 2, wherein the tablet consists of two types of layered pellets, the first type consists of enteric coating layered pellets comprising the H^+, K^+-ATPase inhibitor and the second type consists of pellets comprising the gastric antisecretory prostaglandin analogue, all pellets are compressed together with tablet excipients to a tablet.

26. A tablet dosage form according to claim 22, wherein the tablet consists of enteric coating layered pellets comprising the H^+, K^+-ATPase inhibitor, and pellets comprising the gastric antisecretory prostaglandin analogue incorporated in a matrix giving an extended release of the prostaglandin analogue.

27. A dosage form according to claim 3, wherein the capsule comprises two types of layered pellets, the first type consists of enteric coating layered pellets comprising the H^+, K^+-ATPase inhibitor and the second type consists of pellets comprising the gastric antisecretory prostaglandin analogue, all pellets and optionally pharmaceutically acceptable excipients are filled in the capsule.

28. A process for the manufacture of a fixed dosage form comprising a H^+, K^+-ATPase inhibitor and one or more gastric antisecretory prostaglandin analogue(s) in a capsule, characterized in that the H^+, K^+-ATPase inhibitor is prepared in the form of enteric coating layered pellets, and the gastric antisecretory prostaglandin analogue is prepared in the form of pellets coating layered with an extended release film, the pellets are mixed, optionally with pharmaceutically acceptable excipients, and the mixture is filled in to capsules.

29. A process for the manufacture of a fixed dosage form comprising a H^+, K^+-ATPase inhibitor and one or more gastric antisecretory prostaglandin analogues in a multiple unit tableted dosage form, characterized in that the H^+, K^+-ATPase inhibitor is prepared in the form of enteric coating layered pellets and these pellets are mixed with pellets comprising the gastric antisecretory prostaglandin analogue, and optionally pharmaceutically acceptable tablets excipients, whereafter the mixture is compressed into multiple unit tablets without causing any significant change of the acid resistance of the enteric coating layered pellets.

30. A process for the manufacture of a fixed dosage form comprising a H^+, K^+-ATPase inhibitor and one or more gastric antisecretory prostaglandin analogues in a multiple unit tableted dosage form, characterized in that the H^+, K^+-ATPase inhibitor is prepared in the form of enteric coating layered pellets and the gastric antisecretory prostaglandin analogue is prepared in the form of coating layered pellets wherein the coating layer is an extended release layer, the pellets are mixed, optionally with pharmaceutically acceptable tablet excipients, and compressed into tablets without causing any significant change of the acid resistance of the enteric coating layered pellets.

31. A method for the treatment and profylaxis of gastrointestinal disorders by administering to a host in need thereof a therapeutic effective dosage form according to any of claims 1-27.

32. A method for avoiding gastrointestinal side-effects normally associated with gastric antisecretory prostaglandin analogue medicament treatment in mammals and man by administering to a host in need thereof a therapeutically effective dosage form according to any of claims 1-27.

33. Use of a dosage form according to any of claims 1-27 in the manufacture of a medicament for treatment or profylaxis of gastrointestinal diseases.

34. Use of a dosage form according to any of claims 1-27 in the manufacture of a medicament for avoiding gastrointestinal side-effects normally associated with gastric antisecretory prostaglandin analogue treatment.

35. A combination of a H^+, K^+-ATPase inhibitor, a gastric antisecretory prostaglandin analogue and a calcium channel blocking agent in the treatment of gastrointestinal diseases.

36. A blister pack comprising a H^+,K^+-ATPase inhibitor medicament and a gastric antisecretory prostaglandin analogue medicament.

37. A blister pack according to claim 36 comprising an additional medicament which is a calcium channel blocking agent.